Human Subjects Research Protocol

The Common Human Subjects Protocol Cover Form **must** be completed and accompany this form. This Protocol form should be completed for any human subjects research proposal that does not have a specific "protocol," such as a grant application. This form must be submitted along with a copy of the complete grant proposal and all the information in this form **must** be consistent with that proposal. This protocol form, once IRB approved, will be the working protocol for that research. **When completing this document, do not refer to page numbers within your grant**. If revisions are necessary during the course of the research, amendments should refer to this protocol form, not the grant proposal. Enter responses for all sections. Check N/A if the section does not apply. All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the InfoEd Resource Materials page for more information.

PROTOCOL SUMMARY

Project Title:	Protocol Version Date:
Examining Cooking as a Health Behavior for College Students	04/09/2020

Principal Investigator: Lizzy Pope, PhD, RDN

Grant Sponsor: USDA Hatch Act Funds Grant Number: VT-H02510

(For grants routed through UVM, indicate the OSP Proposal ID # located at the top of the OSP Routing Form)

Lay Language Summary: *(Please use non-technical language that would be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) a brief statement of the problem and related theory supporting the intent of the study, and (2) a brief but specific description of the procedure(s) involving the human subjects. Please do not exceed one single-spaced 8 ½ X 11" page.)*

With the rise in obesity in America correlating strongly with the decline in the frequency that Americans cook at home, cooking may be an important behavior to encourage to promote health. Increasing the prevalence of Americans who cook meals at home may be an important health behavior to target, because cooking at home is widely regarded as being healthier than consuming food away from home. While interventions are limited in number and scope, the positive benefits of cooking at home on dietary quality seem to cut across age groups and populations from college students to older adults.[6, 7]Cooking classes may be an important intervention target because they may increase one's food agency. Thinking of cooking as a health behavior, cooking classes may be equivalent to exercise classes for someone trying to increase their physical activity. The exercise classes give one the skills, social structure, and self-efficacy to begin exercising on one's own. This study is designed to test whether cooking classes could do the same for someone's food agency and cooking frequency.

The proposed pilot study is a trial to evaluate whether cooking classes produce greater gains in cooking skills and food agency compared to a control condition that does not receive cooking classes, as well as whether provision of meal delivery and recipes result in more frequent cooking than no meal delivery or recipes. There will be three phases to the study intervention and four study conditions. All conditions will receive 6 weeks of cooking classes, either active or demonstration, and two conditions will also receive a continued intervention including 6 weeks of meal kit delivery service followed by another 6 weeks of recipe provision.

Phase 1- Cooking classes or control condition. All participants in the cooking classes condition will attend 1 kitchen intensive session followed by 1 cooking class per week for 6 weeks. Control condition participants will receive no cooking instruction.
Phase 2- Meal Kits. Assigned participants will receive meal kit deliveries once per week for 6 weeks.
Phase 3- Recipes. Assigned participants will receive 5 healthy recipes by email once per week for 6 weeks.

We will randomize 64 students to one of four intervention conditions.
Group A (n=16) - Active cooking classes followed by meal kits and recipes
Group B (n=16) - Active cooking classes followed by no further instruction
Group C (n=16) – Control condition followed by meal kits and recipes
Group D (n=16) – Control condition followed by no further instruction

Assessments will be conducted at baseline, and following each phase.

Aim 1: Aim 1: To pilot test a food-agency focused cooking class pedagogy to motivate college students to cook more frequently, improve their diet quality, and increase their sense of food agency.

Aim 2: To evaluate if providing students with six weeks of a meal delivery service and then six weeks of recipes after completion of cooking classes maintains gains in diet quality, cooking frequency, and food agency.

Aim 3: To positively influence participants' stress levels.

Aim 4: To explore the reasons why students cook or do not cook.

Cooking Classes: Those in the Cooking Classes Intervention groups will attend one cooking class per week for six weeks led by a trained chef and based on an established curriculum designed to increase one's food agency, or cooking confidence. Participants will cook one recipe per week as well as participant in various tastings.

Control Condition: Participants in the Control Condition will not attend weekly cooking classes. They will be instructed to cook or not cook as they usually do. They will be asked to complete baseline measures, as well as measures at the end of each intervention period.

Meal Kits: With the meal delivery service, participants will get all the ingredients they need to make a meal as well as a recipe for the meal which includes step-by-step photos. They are then responsible for doing the actual cooking of the meal. Students will all receive kits for 3 meals per week from the same delivery service and will have the option to select meals that fit their dietary needs (vegetarian, gluten free, etc.). Meal kits are designed to serve two individuals therefore students should have enough food for six meals, though they will only need to cook three times. The service used is open to the public, therefore students who enjoyed the meal kit service could opt to continue service and pay for it themselves. However, students will be instructed to wait until study completion to do so.

Recipes: Recipes will be designed by the research team, which includes three registered dietitians and a trained chef. Students will receive recipes for five healthy meals per week. Participants will need to shop, budget, and plan on their own. Recipes will accommodate major dietary preferences including vegetarian and gluten-free.

PURPOSE AND OBJECTIVES

Purpose: *The importance of the research and the potential knowledge to be gained should be explained in detail. Give background information.*

Frequency and Importance of Cooking at Home

Over the last twenty years Americans' eating habits have shifted, with fewer meals cooked at home and more meals eaten outside the home from restaurants, convenience stores, fast food locations, and cafeterias.[1-3] The latest analysis by the United States Department of Agriculture (USDA) Economic Research Service (ERS) indicated that household expenditures on food away from home have been steadily increasing over time and reached 43.7% of food expenditures in 2014.[4] As a percent of total household income, food away from home accounted for 5.4% of disposable income in 2014. Because food away from home is typically far less healthy[5-9] than food eaten at home, it is no surprise that many public health interventions have focused on attempting to make meals away from home healthier. However, Americans still report spending more of their disposable income on food eaten at home (6%), and at least 90% report at least sometimes cooking at home[10]. Regardless, it is clear that with innumerable options available to outsource cooking, this once necessary domestic behavior has declined in recent years in step with the rise of convenience food consumption.[11] In fact, the decline in cooking has been cited as being responsible for the increase in the prevalence of obesity and other chronic disease risk factors.[12] Despite this, few interventions have focused on overcoming the barriers people face to cooking more frequently at home and helping people cook healthy meals at home.[3]

Increasing the prevalence of Americans who cook meals at home may be an important health behavior to target, because cooking at home is widely regarded as being healthier than consuming food away from home. While interventions are limited in number and scope, the positive benefits of cooking at home on dietary quality seem to cut across age groups and populations from college students to older adults.[6,7] A study by Wolfson et al., looking at data from the National Health and Nutrition Examination Survey found that adults who cook dinner frequently at home had diets lower in total energy, fat, and sugar than those who cooked less frequently at home.[13] This association between cooking dinner more frequently at home and a healthier diet was present regardless of whether someone was actively attempting to lose weight or not.[13] Additional research from the USDA ERS has also found that food prepared at home is of higher dietary quality than food prepared away from home, with food prepared away from home associated with diets higher in calories, saturated fat, added sugars, and lower in fruits, vegetables, and whole grains.[8, 9] In addition to research associating cooking at home with better diet quality, there is also evidence that increasing one's cooking knowledge and/or skill is associated with increased healthy food intake.[14, 15] Finally, some research has associated cooking at home with lower Body Mass Index (BMI).[16] Despite all of the evidence indicating that cooking at home should be considered a health behavior, several studies have found that cooking at home is not associated with diet quality or BMI benefits,[17,18] indicating that learning how to cook healthfully at home may be essential for positive health benefits.

In addition to any potential benefits on dietary quality and weight status, it may be the case that cooking positively impacts

social and emotional health.[6] In a survey of young adults, Larson et al., found that eating dinner with others versus eating on the run was associated with higher intakes of fruits and vegetables, and that the majority of young adults surveyed wanted to eat with others, but reported not having enough time.[19] Cooking ability has also been linked to lower depressive symptoms, and higher mental well-being in adolescents, while participation in a culinary intervention was associated with greater quality of life in adults.[20,21] In a review of the literature surrounding cooking and health, Mills et al. even found some evidence that cooking could have positive benefits on cultural identity and personal relationships.[22] All of these findings build the case that cooking at home may impart benefits beyond improving one's diet or weight.

Barriers to Cooking at Home

There are a variety of societal and technological shifts since the 1960's that are often cited as reasons for why Americans cook less frequently at home, such as a notable increase in women joining the workforce, advances in food technology, and mass food preparation.[5] However, on an individual basis, issues such as lack of cooking knowledge, restricted access to healthy foods, economic constraints, and time scarcity have all been cited as potential factors for the decline in home cooking frequency.[5,23,24] Time scarcity is a fascinating concept to consider as a barrier for cooking at home, as there have always been and will always be 24 hours in a day. Therefore, it's not that Americans today have less total time than Americans in the 1960's, but that they choose to, or need to, spend that time differently, and feel that tasks like cooking can be shortened or offloaded to preserve time for other activities.[23] Time scarcity seems to be a cooking barrier for many populations. Many parents report that time scarcity is a barrier to providing healthy meals, and that they often resort to using convenience foods and picking up take out to feed their families.[25] A longitudinal analysis of Australian adults indicated that time scarcity was associated with eating out more, less fruit and vegetable consumption, and higher intakes of discretionary calories.[22] Economic analyses have also indicated that time scarcity is associated with increased intake of fast food.[26] Although much work has illustrated that many people feel that they cannot engage in health behaviors such as cooking because of perceived or actual time scarcity,[22,23] very few intervention studies have examined potential strategies that might decrease people's perceptions of time scarcity and increase the number of days they are willing to cook meals at home.

Encouraging Cooking at Home

While cooking has been associated with a number of positive nutrition and health outcomes, current cooking interventions suffer from a number of methodological limitations.[39] In many, cooking skills or cooking "classes" are rarely presented as a sole component in interventions but are combined with nutrition, exercise, mindfulness, parenting, etc. topics.[pp] It's not clear then if cooking has value alone or just in concert with other treatment components. Current cooking interventions are also quite variable in length; 6-10 weeks of weekly sessions with 90-120 minutes devoted to class. Interventions also differ substantially in the level of engagement participants have with hands on cooking; some simply observe skills while others practice skills and create full meals. Finally, most evaluations of cooking interventions have relied on self-report measures that are rarely validated, thus calling into question the many positive outcomes cited above.[27] A more robust approach to evaluation is desperately needed.

Young adults may be living on their own for the first time, and be in a life stage where learning about cooking and incentivizing cooking would be especially salient.[28] Compared to young adults living on a college campus, young adults who live off campus report less healthy dietary intake and less healthy home food availability.[29, 30] There is also great variation by sex, food/nutrition education, and living situation in the level of cooking skills college students report.[31] Larson et al., found that the majority of young adults surveyed did not perform food preparation and purchasing behaviors such as buying fresh vegetables, writing a grocery list, or preparing dinner.[14] Therefore, there seems to be a need to help young adults living off campus to develop a sense of food agency and cooking skills. Developing these skills is additionally important when considering that results from a 10-year longitudinal study by Laska et al., found that engagement in food preparation during emerging adulthood was associated with healthier dietary intake during the mid-late twenties suggesting that exciting college students to cook may have long-term health benfits.[32]

Cooking classes may be an advantageous way to address many barriers to cooking. Cooking classes can impact time poverty by helping participants learn how to plan meals and easily prepare ingredients.[5] They may also teach budgeting skills to address economic barriers. However, very few rigorous studies have been conducted that design and evaluate cooking interventions in any adult population.[7] Several studies on college students have examined class-based interventions where students in nutrition courses were either asked to cook a healthy entrée or a whole grain and then report back to the instructor or class on the experience.[33, 34] Although students favorably reviewed each cooking activity, these interventions did not include any measures evaluating increase in cooking skills or dietary changes, and did not teach students how to cook. Clifford et al., conducted an intervention study with 101 upper-level college students half of whom watched four 15-minute episodes of a specially-designed cooking show on the internet, and half of whom were randomized to a control group. At the end of the four-week intervention and at a 4-month follow-up those in the intervention group had significant improvements in their knowledge of fruit and vegetable recommendations, but there was no impact on students' skills or dietary behaviors.[35] Therefore, passively receiving information about how to cook fruits and vegetables may not inspire actual behavior change in college students. However, in a study of a Massive Open Online Course (MOOC) focusing on Child Nutrition and Cooking, Adam et al., did find significant positive changes in participants' meal composition and eating behaviors after they were enrolled in the MOOC for five weeks and had to watch 47 four to six minute videos on cooking.[36] Although some of the participants in this study were college aged, the majority were over age 30, and many had children which could have provided additional motivation to learn from the online videos.[36] Reinforcing the idea that interventions that involve active cooking classes may result in the biggest changes in attitudes, knowledge, and behaviors around cooking, Levy and Auld found that college students who attended four cooking classes, had greater shifts in their attitudes and behaviors than students who attended four cooking demonstrations.[37]

A 2018 review by Hollywood and colleagues[38] evaluated the behavior change techniques used in cooking interventions that were most likely to result in long-term behavior change. Fifty-nine cooking and food skills interventions were identified by two systematic reviews. Only 24 interventions included practical cooking sessions to develop cooking skills while all others were based on wider food skills like nutrition knowledge and budgeting. Of the 24 cooking interventions, only 12 were randomized controlled trials. Of those reporting a long-term behavior change (greater than 3 months; n=14), the majority included a "practical skills element" and information on "how to carry out the task" versus just a demonstration of the task. This suggests that food demonstrations are not sufficient to encourage behavior change. The authors also concluded that the vast majority of outcome measures relied on self-report thus, results are to be interpreted with caution.

Fostering Food Agency

Cooking classes may be an important intervention target because they may increase one's food agency. Thinking of cooking as a health behavior, cooking classes may be equivalent to exercise classes for someone trying to increase their physical activity. The exercise classes give one the skills, social structure, and self-efficacy to begin exercising on one's own. This study is designed to test whether cooking classes could do the same for someone's food agency and cooking frequency. Food agency looks at cooking as more than just a manual skill, it takes into account the sensory, socio-cultural (e.g. time, money) and physical environments involved in cooking, and it incorporates the ability to adapt. Those with high food agency feel empowered in their cooking practice, as they have the planning and preparatory skills, as well as the cooking skills to be successful.[28] Trubek et al., have developed a pedagogy for cooking classes designed to increase food agency by addressing the cognitive, technical, and mechanical skills necessary to make a meal.[oo, 28] By using pedagogy designed to increase one's food agency, the participant is better prepared to overcome potential daily challenges that could prevent them from meeting their cooking, nutrition, and social goals. The pedagogy emphasizes not just skill building like how to read and use a recipe, but adaptability and the development of decision-making and organizational skills that will be helpful no matter the food environment, time, or resource limitations.[40] The concept of food agency views cooking behavior in a more holistic way. It is not enough to just teach someone the mechanics of cooking, in order for cooking to become an ingrained practice, you must teach someone how to overcome barriers and adapt to the conditions they face in daily life. Like many other health behaviors, encouraging someone to cook will only be successful if that person feels empowered to take the practice and apply it in their own life to form a habit.

Increasing Motivation to Adopt Cooking as a Health Behavior

Along with teaching cooking competency through a pedagogy that emphasizes food agency, it may be helpful to provide a material incentive to help overcome remaining barriers to healthy cooking. Incentives have been deployed successfully for a variety of health behaviors and health outcomes such as exercise and weight loss.[29,30] Incentives can be offered in many forms, on a variety of schedules, and in various amounts. As provisioning food, deciding what to buy, and having the resources to buy it, are often cited as barriers to cooking at home, it may be the case that providing people with meals and/or recipes each week could serve as incentives to overcome the provisioning barrier and encourage people to implement the skills learned during their cooking classes. Recently, meal kit delivery services such as Hello Fresh, Blue Apron, and Purple Carrot have risen in popularity.[31] These services provide subscribers with the raw ingredients in the correct amounts necessary to make particular recipes and then also provide the recipes. Previous research has shown that providing participants with food increases their weight loss,[32] but there is very little research indicating if providing food has a positive impact on cooking behavior or diet quality.

Summary

The current study will expand on previous research surrounding the efficacy of employing cooking classes to build cooking skills, foster food agency, and improve dietary behaviors by employing a rigorous controlled trial design and validated outcome measures in college students. The overall goal is to determine if encouraging cooking as a health behavior actually improves health outcomes.

***References**. Include references to prior human or animal research and references that are relevant to the design and conduct of the study.*

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Objectives: *Clearly state the primary and secondary objective(s) of the study.*

Objectives: The purpose of the study is to examine the impact of completing a set of cooking classes on college students' cooking frequency, food agency, and diet quality. After completion of six cooking classes we will also examine whether providing students with material support in the form of meal delivery boxes and recipes better maintains any gains in cooking frequency, diet quality, or food agency from the classes. Finally, throughout the study we will collect qualitative data exploring the reasons why students choose to cook or not cook at home.

Aim 1: To pilot test a food-agency focused cooking class pedagogy to motivate college students to cook more frequently, improve their diet quality, and increase their sense of food agency.

Hypothesis 1.1: Students in the intervention (cooking) condition will experience greater positive changes in food agency, cooking frequency, and diet quality outcomes after six weeks of cooking classes compared to students in the control condition.

Aim 2: To evaluate if providing students with six weeks of a meal delivery service and then six weeks of recipes after completion of cooking classes maintains gains in diet quality, cooking frequency, and food agency.

Hypothesis 2a: Meal delivery service will better maintain cooking frequency, food agency and diet quality versus recipe provision only. Both meal delivery service and recipe provision only will result in more frequent cooking, higher food agency, and higher diet quality than the provision of no cooking support.

Hypothesis 2b: During both meal delivery service provision and recipe provision, those in the Cooking Class Condition will maintain higher levels of food agency, cooking frequency, and diet quality than those in the Control Condition.

Aim 3: To positively influence participants' stress levels.

Hypothesis 3: Participants receiving cooking support will have lower scores on a measure of perceived stress than participants who do not receive cooking support. This will be true at all measurement time points.

Aim 4: To explore the reasons why students cook or do not cook.

Hypothesis 4: There will be common themes defining why student choose to cook or not cook at home.

METHODS AND PROCEDURES

Study Design: *Describe the research design, including a description of any new methodology and its advantage over existing methodologies.*

We propose a randomized trial to evaluate whether cooking classes produce greater gains in cooking skills and food agency compared to a control condition, as well as whether provision of meal delivery and recipes result in more frequent cooking than no meal delivery or recipe provision. We will randomize 64 students to either the intervention condition where they will take part in six weeks of hands on cooking classes, or the control condition where they will receive no cooking instruction during the fall semester. Following the completion of cooking classes and the start of the spring semester, one active cooking (treatment) group and one control group will receive another 12 weeks of intervention while the other two groups will receive no further instruction. The two continued intervention groups will be subscribed to a meal delivery service for six weeks, and then receive only recipes for another six weeks. Assessments will be conducted at baseline and following each phase of the intervention for all groups.

Study Population

The target population for this study is all undergraduate students at UVM living off-campus in an independent housing arrangement where they have access to a kitchen. As most junior and senior students live off campus, we expect to recruit mostly junior and senior students. In Spring 2017 there were 2,232 juniors and 2,926 seniors enrolled at UVM, indicating that over 5,000 students could be eligible for the study. For the first two years at UVM, the majority of students live in dorms on campus and are required to have meal plans. The majority of juniors and seniors at UVM then move off campus. This time frame may encompass the first time that many students have had to consider buying and cooking food for themselves. Addressing cooking behaviors during this transition may help establish lifelong cooking habits. Participants will need to have access to a kitchen because the study examines how to influence and increase cooking behaviors. Participants may have roommates with whom they share a kitchen, however they will not be eligible if they live with parents or guardians, as in this scenario they likely have less required independence around cooking. Participants who already cook dinner at home four times per week or more will not be included in the study, as they are already cooking at home frequently and do not need to be motivated to do so. Previous research has indicated that the majority of college students do not prepare dinner even weekly, so we do not anticipate this inclusion criteria greatly restricting our sample.[14]

Inclusion criteria:

- Student at the University of Vermont
- Age 18-25
- Cooks dinner at home no more than 3x/week
- Access to a kitchen at home
- Lives independently (may have roommates but may not live with guardians)
- Availability during scheduled cooking classes/demonstrations

Phase 1: The Cooking Program

Active Intervention. Six cooking classes will be held every week for six consecutive weeks. The cooking lessons will be patterned after Dr. Amy Trubek's cooking pedagogy and will be tailored for individuals cooking for themselves for the first time. Classes will begin with a brief lecture on the day's topic, followed by a laboratory session. Participants work in teams of two in the NFS foods lab to actively practice skills and cook a meal. Subjects will receive recipes and information sheets that cover pantry supplies, grocery lists, knife skills and cooking equipment. Classes will be taught by a chef trained in the pedagogy by Dr. Trubek and participants will have the opportunity to sample the food they prepared at the end of class.

Kitchen Intensive. As part of the orientation process, participants will attend a 2-hour kitchen intensive demonstration. This demonstration will introduce participants to the kitchen lab space and cover basic kitchen skills including food safety, sanitation, equipment overview, and the basic principles of food agency.

Control Condition. Those in the Control Condition will receive no cooking support over the fall semester. They will serve as a benchmark for how college students normally cook without focused instruction. They will be asked to fill out all measures at baseline and throughout the intervention and will be incentivized to do so.

Phase 2 and Phase 3: Follow up Support

The active and control groups receiving follow up support (groups A and C) will receive six weeks of meal kits immediately following the start of the spring semester. Participants in these groups will receive a single delivery each week that will contain three dinner meal kits designed to feed 2 people. The kits will contain all of the ingredients and instructions needed to prepare the recipes, though participants must cook the meals themselves. After six weeks of receiving meal kits, groups will receive five healthy recipes via email per week. Recipes will be designed by the research team, which includes three registered dietitians and a trained chef. Participants will need to shop, budget, and plan on their own.

Procedures: *Describe all procedures (sequentially) to which human participants will be subjected. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes. Describe the types, frequency and duration of tests, study visits, interviews, questionnaires, etc. Include required screening procedures performed before enrollment and while on study. Please provide in table, list or outline format for ease of review. (describe and attach all instruments)*

Note: A clinical research protocol may involve interventions that are strictly experimental or it may involve some aspect of research (e.g., randomization among standard treatments for collection and analysis of routine clinical data for research purposes). It is important for this section to distinguish between interventions that are experimental and/or carried out for research purposes versus those procedures that are considered standard therapy. In addition, routine procedures performed solely for research purposes (e.g., additional diagnostic/follow-up tests) should be identified.

Recruitment: A multipronged recruitment strategy will be used for this study. Recruitment will take place in late summer and fall of 2019. Interested students will be recruited through the weekly University announcement emails. The opportunity to participate will also be advertised on the Junior and Senior classes' social media pages. We will work with the UVM Office of Student and Community Relations to email students who live off campus and may be eligible for the study. Finally, we will set up tabling events in the Davis Center and in front of the library to reach interested students. Interested students will be directed to an online application that offers detailed information about the study and their responsibilities should they choose to participate. The application will also ask the applicant to complete a set of primary screening questions. Individuals who appear eligible based upon the initial screening questions will be invited to an in-person, group information session where they will receive detailed information about the study and informed consent will be distributed. Students will be instructed to carefully review the consent form and consult with anyone they feel can help them make a decision regarding participation. Students will be encouraged to take their time considering the study and to contact study personnel with any questions or concerns they have. Once a student has decided they would like to participate, they will be instructed to contact study personnel and arrange an individual meeting where they will review and sign consent with a member of the study team. If students wish to sign consent immediately following the information session, they will be instructed to wait until the information session has concluded and meet with a member of the study team in a separate office space to complete the consent process. Students will all finish the information session together and exit the meeting space. Only those interested in signing consent immediately will walk down the hall to the office space where the consent process will take place. There will be two exits from the information session meeting space (in Marsh Life Sciences) and there are multiple exits from the building, so students will not be exiting single file. These arrangements should ease pressure on students who are not ready to sign consent or who know they do not want to participate, even if a majority of students in attendance decide to sign consent.

Following signed consent participants will be asked to complete a few baseline tasks to be fully eligible for participation in the study. These tasks include three days of food tracking using ASA-24, baseline surveys, submission of cooking frequency and food photos, and finally a one-on-one interview with study staff to discuss their participation. These baseline tasks are intended to ensure participant compliance and retention during the 18-week intervention.

Eligible participants will be assigned to one of four scheduled class periods based on their stated availability or recruited for the control condition. Once all classes are full, a random assignment table will be used to determine the group assignment for each class period. Participants will then be informed of their group assignment (active with follow up oractive no follow up). Participants who are in the control condition will be randomly assigned to either a group that receives follow-ups or a group that does not. Groups will not be stratified by any criteria, and instead will be determined based upon participant availability.

Surveys will be administered through the study REDCap website at baseline and study end. Participants will receive links to the questionnaires and reminders to complete questionnaires via email. These measures are outlined in greater detail below. In addition to questionnaires, weekly data collection (Photo Elicitation and Cooking Frequency) will be administered through REDCap. Participants will receive a weekly email with links to a REDCap data collection tool. Participants will receive reminders to complete weekly data submissions, and will be given information regarding a helpline for using the study website and data entry.

Table 1 outlines when each measure will occur during the study.

Measures	Baseline	Weekly	Phase 1	Phase 2	Phase 3
ASA24					
HEI (calculated)					
CAFPAS					
Cooking Perceptions and Behaviors					
PSS					
Intuitive Eating Scale					
Interoceptive Awareness					
Cooking Frequency					
Photo Elicitation					
Class Evaluation					
Meal Kit Evaluation				X	
COVID-19 Questionnaire					X

Quantitative Measures

Automated Self-Administered 24-Hour Dietary Assessment Tool (ASA24) – The ASA24 is a web-based dietary assessment tool developed by the National Cancer Institute that allows collection of multiple, automatically coded, self-administered 24-hour recalls. The ASA24 has been validated and used in many different populations and nutrition studies.[41] When completing the ASA24, the participant is first prompted to report the time of all food and drinks consumed. Next, they search a list of foods and select which foods they ate at each meal. If there is a gap of more than three hours between reported eating occasions participants are then asked if they ate anything during that gap. There is then a detail pass where participants are asked about preparation methods, portion sizes and anything they added to a food. Finally, participants are asked about foods and beverages that people commonly forget to include and can add any of these items to their recall. Detailed instructions with pictures for completing the recall are available on the ASA24 website and participants will be made aware of this resource.
Foods included in the ASA24 all code to the USDA's Food and Nutrient Database for Dietary Studies, and so all entries can be automatically coded.[41]

Healthy Eating Index (HEI) – The HEI is a measure of overall diet quality, and can assess compliance with the U.S. Dietary Guidelines, as well as measure changes in dietary patterns. The HEI is updated with each set of Dietary Guidelines, and has been validated for the 2005 and 2010 Dietary Guidelines.[42] The HEI is a valid and reliable tool for assessing dietary quality in a variety of population subgroups and nutrition interventions.[42] The validation for the 2015 Dietary Guidelines is expected soon. The HEI takes into account one's intake of the following foods when calculating a total score, total fruit, whole fruit, total vegetables, dark green vegetables, legumes, whole grains, dairy, total protein foods, seafood, eggs, soy products, nuts and seeds, refined grains, saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, sodium, calories from added sugars, and total calories.[42] The HEI calculates final scores from 24-hour recalls like the ASA24.

Cooking and Food Provisioning Action Scale (CAFPAS): The CAFPAS scale measures cooking and food preparation practices or the degree to which individuals can set and achieve cooking and food provisioning goals. The CAFPAS includes 28 items with three subscales: Food Self-Efficacy, Food Attitude, and Structure. The CAFPAS scale has been shown to predict reported meals cooked per week and has adequate internal validity and test-retest reliability.[43]

Perceived Stress Scale (PSS) – The PSS is a reliable and valid measure of perceived stress in adults including college students.[59] It is composed of ten questions that assess how often one perceives various forms of stress such as feeling unable to control important events, being upset by something unexpected, and feeling nervous.[59] Every six weeks participants, during the study period, participants will fill out the PSS, so any impact of cooking practice on stress can be illuminated.

The Cooking Perceptions and Behaviors Questionnaire: The Cooking Perceptions and Behaviors questionnaire is a 53-item survey designed to assess three factors: Perceptions of Cooking, Cooking Confidence and Attitudes, and Cooking Behaviors. This survey has been used in previous research to measure cooking perceptions and behavior.[44]

Intuitive Eating Scale-2: The Intuitive Eating Scale-2 is a 23-item survey designed to assess the degree to which someone is able to listen to hunger and fullness cues when they decide what, when, and how much to eat.[45] The scale is composed of four sub-scales, Unconditional Permission to Eat, Eating for Physical Rather Than Emotional Reasons, Reliance on Hunger and Satiety Cues, and Body-Food Choice Congruence. This survey has been used in previous research with college students.[45]

Interoceptive Awareness - Research has indicated that there is an association between interoceptive awareness and intuitive eating. Interoceptive awareness is the ability to detect internal bodily cues.[46,47] One way to measure interoceptive awareness in individuals is to determine their ability to count the number of times they perceive their heart to beat during a given period of time.[46] We will ask subjects to perceive their heartbeat for 30 seconds, and then report their result. Next, we will to take their wrist pulse for 30 seconds. We will compare heartbeat perception accuracy to Intuitive Eating scores, to determine any association in college aged students. Participants will be asked if they would like to complete the interceptive Awareness exercise during phase I cooking classes, but may opt not to participate.

Weekly Assessment of Cooking Frequency: Each week, participants will complete a brief survey to record how many times that week they cooked at home. The weekly surveys should take 5 minutes or less to complete.

COVID-19 Questionnaire – At the conclusion of the study all participants will be asked to answer questions related to changes that occurred to their living situation and food access as a result of the COVID-19 outbreak and subsequent social-distancing measures.

Qualitative Measures

Photo Elicitation – Using photo elicitation, participants take photos of a particular topic and then these photos are used as the starting point for an interview between the participant and researcher. Photo elicitation has been used in public health research previously with a variety of projects and populations.[48] For this study, participants will be asked to take photos with their smartphones or cameras and then upload two photos each week to REDCap via the weekly email link. Instructions will ask participants to capture the meal that week they feel most represents their interpretation of a "healthy meal," and the meal they ate that week that *least* represents their interpretation of a "healthy meal." Both the intervention and control group will be instructed to take these weekly photos and label them as a meal they cooked at home or a meal they did not cook at home. At

the conclusion of the study, investigators will randomly select five participants from each group to interview about their photos. The interviews will ask questions about why the photos represented healthy or unhealthy meals to the participants, where the meals were prepared, how the photos may have changed over time, and how the various interventions may have affected the photos.

Cooking Class Evaluation – At the conclusion of the cooking classes for the intervention group there will be a class evaluation given to assess participants' impressions of the classes or demonstrations. This evaluation will be available on the study website, and participants will have time in class to complete the evaluation and can do so on their smart phone or tablet. Participants will also have the option to complete this evaluation at a later time on their home computer.

Meal Kit Evaluation – At the conclusion of the Meal Kits (Phase 2) participants in Groups A and C (those receiving the meal kit intervention) there will be an evaluation given to assess participants' impressions of the meal kits they received. The evaluation will be included in the emailed set of surveys for participants in Groups A and C.

Intervention
Phase 1 will being in October of 2019. Participants in all active cooking groups will attend a weekly 2-hour cooking class to learn how to prepare the same meals. Participants will sample the meal at the end of class and the chef will walk them through a sensory exercise. At the end of each class, participants will be provided with the recipe for the next class and asked to create a timeline for the various steps of preparation. Participants will bring this timeline to class and discuss as a group before preparing the meal or watching the demonstration.

After the final cooking class, participants in groups B and D will receive no further instruction, though they will be asked to complete surveys and data collection through the remainder of the study phases. Phase 2 will begin in mid-January 2020. Participants in Groups A and C will receive weekly meal kit deliveries for 6 weeks. Meal kits will be delivered to students' homes once per week and will include the ingredients and instructions for preparing 3 separate meals. Phase 3 will being immediately following phase 2. Participants in groups A and C will receive an email at the beginning of each week for the next six weeks that provides them with 5 healthy recipes developed by the study team. Students will generally receive the same recipes though; modifications may be made for participants with special dietary restrictions.

Facilities and Equipment Needed
Cooking Labs – The cooking classes and demonstrations will take place in the Nutrition and Food Sciences teaching kitchen located in the Marsh Life Science building. The teaching kitchen has room for 16 students to complete hands on cooking labs, and an additional space where students can get directions, eat, and watch cooking demos. The kitchens are fully stocked with the necessary kitchen equipment.

Follow-up Data Collection
Participants will be alerted by email to complete their follow-up assessment questionnaires which are anticipated to take approximately 30 minutes to complete and 3 days of the ASA24 (approximately 30 minutes per day).

All participants will be offered small incentives such as cooking equipment, cookbooks, gift cards, etc. (valued at approximately $ 5-25) after completion of the follow-up data collection. Those in the Control Group will also receive a small incentive for completing their baseline measures.

For research involving survey, questionnaires, etc.: *Describe the setting and the mode of administering the instrument and the provisions for maintaining privacy and confidentiality. Include the duration, intervals of administration, and overall length of participation. (describe and attach all instruments)*

☐ ***Not applicable***

Questionnaires and ASA-24 logs will be administered at baseline and at the end of each study phase.

Photo elicitations and cooking frequency surveys will be administered weekly during the active study phases.

Surveys questionnaires, and photo elicitations will be administered online through the study website (REDCap). Participants will be sent links to questionnaires and surveys through their email. Participants will be able to save and return to questionnaires with a unique 8 digit ID provided by REDCap, however participants will not have access to review the questionnaires after completion or to make changes after submitting the forms. They will be provided with a helpline contact should they encounter difficulty in completing the forms. If participants prefer, they can complete the forms using a paper copy rather than online. It is expected that the online baseline and follow-up assessment questionnaires will take less than 30 minutes to complete.

ASA-24 logs will be administered through the ASA-24 respondent website. Each participant will have a unique ID and password that will be used to log in to the website. Participants will be provided with an ASA-24 Getting Started Guide and a helpline should they have trouble using the website. The baseline and follow-up ASA24 3 day tracking is estimated to take approximately 30 minutes for each entry.

Surveys, questionnaires, and ASA-24 logs will all be identified by a unique study ID number. Participant names and other identifying information will not appear on any materials except for the initial study application. The name field will be flagged as an identifier in REDCap so that it may be excluded from data analysis. A password-protected master key will be maintained solely by the research coordinator and PI.

Statistical Considerations: *Delineate the precise outcomes to be measured and analyzed. Describe how these results will be measured and statistically analyzed. Delineate methods used to estimate the required number of subjects. Describe power calculations if the study involves comparisons. Perform this analysis on each of the primary and secondary objectives, if possible.*

Aim 1: To pilot test a food-agency focused cooking class pedagogy to motivate college students to cook more frequently, improve their diet quality, and increase their sense of food agency.

Hypothesis 1. Students in the intervention (cooking) condition will experience positive changes in food agency, intuitive eating, cooking frequency, and diet quality outcomes after six weeks of cooking classes compared to students in the control condition.

A repeated measures ANOVA analysis will be used to compare changes in intuitive eating, diet quality and food agency over time both within the groups and between the groups. A generalized linear mixed model design will be used to compare the frequency of cooking at home each week over time and between the groups.

Aim 2: To evaluate if providing students with six weeks of a meal delivery service and then six weeks of recipes after completion of cooking classes maintains gains in diet quality, cooking frequency, intuitive eating, and food agency.

Hypothesis 2a: Meal delivery service will better maintain cooking frequency, intuitive eating skills, food agency and diet quality versus recipe provision only. Both meal delivery service and recipe provision will result in more frequent cooking, higher food agency, and higher diet quality the provision of no cooking support.

Hypothesis 2b: During both meal delivery service provision and recipe provision, those in the Cooking Class Condition will maintain higher levels of food agency, cooking frequency, and diet quality than those in the Control Condition.

Repeated measures ANOVA analyses will be used to compare between subjects effects from the meal delivery and recipe only interventions, as well as to compare the material support interventions against the control group. Repeated measures ANOVA will also be used to compare within subjects effects from end of fall semester to the end of each six-week material support intervention.

Aim 3: To positively influence participants' stress levels.

Hypothesis 3: Participants receiving cooking support will have lower scores on a measure of perceived stress than participants who do not receive cooking support. This will be true at all measurement time points.

A repeated measures ANOVA will be used to determine differences both between groups and over time in scores of perceived stress.

Aim 4: To explore the reasons why students cook or do not cook.

Hypothesis 4: There will be common themes defining why student choose to cook or not cook at home.

This is an exploratory aim, and qualitative analysis will be used to deduce popular themes.

Sample Size

This is a pilot study with no previous data available to calculate expected statistical power. The sample size chosen was practical as our foods lab can only accommodate 16 people at a time. Two intervention groups and two control groups for each study phase will provide data on approximately 64 subjects. This preliminary data will be used to determine the sample size power needed for a larger study with sufficient statistical power.

Risks/Benefits: *Describe any potential or known risks. This includes physical, psychological, social, legal or other risks. Estimate the probability that given risk may occur, its severity and potential reversibility. If the study involves a placebo or washout period, the risks related to these must be addressed in both the protocol and consent. Describe the planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits to subjects and others. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research and why the risks are reasonable in relation to the knowledge that reasonably may result. If there are no benefits state so.*

Potential Risks.
No social, legal or other risks are anticipated as part of this project. All assessment procedures and intervention recommendations have been used in previous studies without adverse outcomes. Assessment methods reflect measures that have been implemented in numerous studies without difficulties (e.g., dietary intake and cooking behavior questionnaires).

Intervention methods are similarly very low risk. There is a risk of accidental injury during the active cooking classes. Participants will be using gas stoves, knives, and other kitchen equipment. Study staff will take precautions in preparing participants to safely handle all kitchen equipment. All participants will be required to attend the Kitchen Intensive session before taking part in a cooking class. This session will ensure that all participants are equipped with basic food and equipment safety information. Prior to each cooking class, the chef with outline equipment to be used that day and any safety concerns regarding those specific pieces of equipment. Additionally, the chef, along with trained research assistants, will monitor participants closely during active cooking classes to ensure that they are using equipment appropriately. Procedures detailing how to handle an accident or injury will be posted in the kitchen. All study staff and all participants will be instructed to locate these procedures and review them during the Kitchen Intensive session.

Every effort will be made to keep participants' information private and confidential. Confidentiality will be ensured by coding data with a unique ID number, and all data collected will be stored in locked files with access restricted to study personnel, and password protected computer data files. Participants will not be personally identified in any scientific reports generated by the study or any other dissemination efforts. All results will be presented in aggregate form. All project staff will undergo training and ongoing continuing education about methods to protect confidentiality.

Potential Benefits
The potential benefit to the participants will be the skills and knowledge in cooking behaviors to successfully plan and prepare meals at home. This study will expand our understanding of cooking's potential as a health behavior, by testing several novel interventions, including a cooking pedagogy designed to increase food agency, and provision of material support for cooking at home. Very little previous research has addressed cooking at home as a potential health behavior. Even less previous work has attempted to motivate people to cook at home. Furthermore, the pedagogy to be used for the cooking class intervention in this study has been explicitly designed to increase one's food agency, a new theoretical concept, that aims to empower one's cooking practice. The relationship between food agency and health has not been explored thoroughly, and this study will examine associations between food agency, cooking at home, diet quality, and psychological (stress) outcomes. In addition to using a new methodological scale associated with food agency, the proposal will use the qualitative technique of photo elicitation to gather qualitative evidence of participants' cooking experiences, perceptions, and barriers.

Therapeutic Alternatives: *List the therapeutic alternatives that are reasonably available that may be of benefit to the potential subject and include in the consent form as well.*

X | ***Not Applicable***

Data Safety and Monitoring: *The specific design of a Data and Safety Monitoring Plan (DSMP) for a protocol may vary extensively depending on the potential risks, size, and complexity of the research study. For a minimal risk study, a DSMP could be as simple as a description of the Principal Investigator's plan for monitoring the data and performance of safety reviews or it could be as complex as the initiation of an external, independent Data Safety and Monitoring Board (DSMB). The UVM/UVM Medical Center process for review of adverse events should be included in the DSMP.*

Safety of the subjects. The proposed study poses no serious physical, psychological, or legal risks to participants. Therefore, the trial will be monitored by the PI's (Jean Harvey, PhD, RD and Lizzy Pope, PhD, RD), the Research Project Coordinator (Mattie Alpaugh, MS, RD) and group facilitators. Weekly meetings or conference calls will be held to evaluate the status of study participants. Any serious adverse events will be recorded on a standard form and reported to the Research Coordinator, to the PI's and the UVM IRB.

Data. Research participants will complete some questionnaires online as dictated by the study protocol. Only their subject identification number will appear on the questionnaires; no names or other personal identifiers will be included on data collection forms. The only exception being the study application, where a name will be collected but marked as an identifier. All data collected by the research coordinator is considered part of the participant's confidential record. Data collected from research participants will be stored as password protected electronic data files. All data will remain confidential. A file will be maintained that associates the participant name with that participant's study identification. This file will remain in a locked file cabinet at UVM and will not be stored with the actual study data. This file will be destroyed at the end of the study.

Storage of Collected Data. All electronic data will be stored in password-protected files. Data will only be accessed when coded or audited. The study's project manager will work closely with the UVM Medical Biostatics facility to ensure the secure storage of all project data, using appropriate data safety procedures. Site specific data, or data not initially entered into REDCap will be sent to the study statistician using secure FTP transfers. All original transferred data files will be stored on a dedicated PC with limited and secured password protected access in a private locked office. Data management and editing of these files will take place prior to archiving any data files into a SAS based project specific database with specific

documentation of any editing and data review adjudications while the original data files will be retained intact. Only archived data files will be used to derive analysis data files to address specific hypotheses or project monitoring reports

The data entry system will require a login identification and password in order to gain access to the data. Where appropriate, validation and range rules will be applied to the actual entry field. Only the Biostatistics staff will be able to view the data in its raw state. All other authorized personnel (Principal Investigators, Research Coordinator) will view data via forms and reports created by the Biostatistics staff.

Direct Data Entry by Participants. Questionnaires will be completed by participants directly online. These questionnaires will utilize formats that include range and validity checks, as appropriate, as well as queries to assure that all items have been answered before completing the form, to assure the most accurate data collection and will be identified only by unique participant IDs. Participants will not have access to review the questionnaires after completed or to make changes after submitting the forms. Participants will be provided with a "helpline" contact should they encounter difficulty in completing the forms.

Access to Cleaned Computer Data. Once the study is complete, and all data have been collected, entered, and passed the verification process, the director of the Bioinformatics facility, will make the data available to the Principal Investigators and their designates. Only the Principal Investigators can give permission for the release of aggregated study data. No confidential information may be released without the express written consent of the study participants. Only copies of the aggregated, de-identified finalized data will be released.

Adverse Event and Unanticipated Problem (UAP) Reporting: *Describe how events and UAPs will be evaluated and reported to the IRB. All protocols should specify that, in the absence of more stringent reporting requirements, the guidelines established in the Committees on Human Research "Adverse Event and Unanticipated Problems Reporting Policy" will be followed. The UVM/UVM Medical Center process for review of adverse events and UAPs to subjects or others should be included in the DSMP.*

Weekly meetings or conference calls will be held to evaluate the status of study participants. Any serious adverse events will be recorded on a standard form and reported to the Research Coordinator, to the PI's and the UVM IRB.

Withdrawal Procedures: *Define the precise criteria for withdrawing subjects from the study. Include a description of study requirements for when a subject withdraws him or herself from the study (if applicable).*

Participants may withdraw from the study at any time by notifying the PI or Study Coordinator in writing (or by email) of their intention.

If necessary, subjects may be terminated or withdrawn by the Principal Investigator without the consent of the participant if continued participation would be contraindicated, including because the participant moves more than 120 miles from the university with no plans to return during study intervention phases.

Sources of Materials: *Identify sources of research material obtained from individually identifiable human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.*

The demographic, behavioral, and self-report questionnaire data collected in this study will be obtained for research purposes only.

DRUG AND DEVICE INFORMATION

Investigators are encouraged to consult the UVM Medical Center Investigational Pharmacy Drug Service (847-4863) prior to finalizing study drug/substance procedures.

Drug (s) [X] ***Not applicable***

Drug name – generic followed by brand name and common abbreviations. Availability – Source and pharmacology; vial or product sizes and supplier. If a placebo will be used, identify its contents and source. (attach investigational drug brochure)

Preparation: Reconstitution instructions; preparation of a sterile product, compounded dosage form; mixing guidelines, including fluid and volume required. Identify who will prepare.

Storage and stability – for both intact and mixed products.

Administration – Describe acceptable routes and methods of administration and any associated risks of administration.

Toxicity – Accurate but concise listings of major toxicities. Rare toxicities, which may be severe, should be included by indicated incidence. Also adverse interactions with other drugs used in the protocol regimen as well as specific foods should be noted. Address significant drug or drug/food interactions in the consent form as well. List all with above details.

Is it FDA approved: (include FDA IND Number)

1. *in the dosage form specified? If no, provide justification for proposed use and source of the study drug in that form.*
2. *for the route of administration specified? If no, provide justification for route and describe the method to accomplish.*
3. *for the intended action?*

Device (s) [X] ***Not applicable***

Device name and indications (attach investigational device brochure)

Is it FDA approved: (include FDA IDE Number)

1. *for indication specified? If no, provide justification for proposed use and source of the device.*

Risk assessment (non-significant/significant risk) - PI or sponsor needs to assess risk of a device based upon the use of the device with human subjects in a research environment.

SUBJECT CHARACTERISTICS, IDENTIFICATION AND RECRUITMENT

Subject Selection: *Provide rationale for subject selection in terms of the scientific objectives and proposed study design.*

This study aims to evaluate changes in food agency including cooking frequency between the two interventions. Therefore, subjects are selected to provide a sample of individuals positioned to increase their food agency and cooking frequency. Towards this end, only individuals who are cooking (from scratch) no more than 3 meals at home per week will be eligible. Additionally, all participants must have daily access to a kitchen with basic appliances and equipment (stove, oven, refrigerator, sink).

All participants must have weekly access to a computer or smart device with internet access in order to report photo elicitations and cooking frequencies. The study does not seek to introduce use of this technology to naïve users who have no daily access. Furthermore, potential participants will be required to demonstrate some ability to comply with study intervention procedures to be eligible. Specifically, they must complete an online dietary self-monitoring diary for 3 days, photo elicitations, and cooking frequency surveys so that only adequately motivated individuals who are likely to stay engaged for the full 18-week study period are enrolled and randomized.

Vulnerable Populations: *Explain the rationale for involvement of special classes of subjects, if any. Discuss what procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risk (physical, psychological, etc.).*

[X] ***Not applicable***

Number of Subjects: *What is the anticipated number of subjects to be enrolled at UVM/UVM Medical Center and in the case of a multi-center study, with UVM/UVM Medical Center as the lead, the total number of subjects for the entire study.*

This is a pilot study with no previous data available to calculate expected statistical power. The sample size chosen was practical as our foods lab can only accommodate 16 people at a time. One group of each intervention arm (four) would give us data on approximately 64 subjects. This preliminary data will be used to determine the sample size power needed for a larger study with sufficient statistical power.

Inclusion/Exclusion Criteria: *Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom. Changes to the eligibility criteria at a later phase of the research have the potential to invalidate the research.*

Interested individuals will be directed to a study application that provides details about the study program and asks a series of screening questions. These questions are intended to determine basic eligibility for the study. Ineligible applicants will be notified of their ineligibility and directed to other campus resources related to cooking and meal planning. Eligible applicants will be directed to sign up for an in-person information session.

Inclusion criteria:

- Student at the University of Vermont
- Age 18-25
- Cooks dinner at home no more than 3x/week
- Access to a kitchen at home
- Lives independently off campus (may have roommates but may not live with guardians)
- Availability during scheduled cooking classes/demonstrations

Individuals will be excluded from the study if they do not complete baseline data collection measures prior to the first class meeting. Baseline data measures include four questionnaires (PSS, CAFPAS, Cooking Behavior, and intuitive eating scale), three days of ASA-24 logs, one photo elicitation survey, and one cooking frequency survey.

Inclusion of Minorities and Women: *Describe efforts to include minorities and women. If either minorities or women are excluded, include a justification for the exclusion.*

Women and minorities will be included. During recruitment, we will work with UVM Office of Student and Community Relations to ensure that our recruitment materials and procedures capture eligible students of all demographics.

Inclusion of Children: *Describe efforts to include children. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When included, the plan must also describe the expertise of the investigative team in working with children, the appropriateness of the available facilities to accommodate children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.* ***If children are excluded*** *then provide appropriate justification. Provide target accrual for this population.*

We propose to exclude children under 18 years of age. Our study is aimed at examining cooking behaviors or college students as they transition into independent living.

For protocols including the use of an investigational drug, indicate whether women of childbearing potential have been included and, if not, include appropriate justification.

Not applicable

If HIV testing is included specifically for research purposes explain how the test results will be protected against unauthorized disclosure. Include if the subjects are to be informed of the test results. If yes, include the process and provision for counseling. If no, a rationale for not informing the subjects should be included.

X ***Not applicable***

Recruitment: *Describe plans for identifying and recruitment of subjects. All recruitment materials (flyers, ads, letters, etc) need to be IRB approved prior to use.*

Participants will be recruited from the University of Vermont student body. Interested students will be recruited through the weekly University announcement emails, university listservs, and flyers. The opportunity to participate will also be advertised on the Junior and Senior classes social media pages. We will work with the UVM Office of Student and Community Relations to email students who live off campus and may be eligible for the study. Finally, we will set up tabling events in the Davis Center and in front of the library to reach interested students. We will recruit 64 students to participate in the study.

Recruitment materials will ask participants to take part in a study on college students, cooking behavior, and health. Materials will list the study inclusion criteria, and explain that students will all receive incentives for completing study assessments. Recruitment materials for the intervention portion of the study will also explain that participants will have the opportunity to participate in a seven-week series of cooking classes, as well as a chance to receive free meal kits for 6-weeks.

Interested persons will be directed to a secure online recruitment application, which provides an outline of the study and queries for basic contact information, demographic information, and eligibly criteria. Individuals who appear likely to be eligible based on this online application will sign up for an in-person information session conducted by research staff during which the study will be reviewed in detail, questions will be addressed and an informed consent document will be provided to take home. After considering the study (participants will have a minimum of 1 week), interested participants will be asked to sign a consent form at the first baseline data collection visit. Consent forms will have been approved by the University of Vermont Institutional Review Board.

FINANCIAL CONSIDERATIONS

Expense to Subject: *If the investigation involves the possibility of added expense to the subject (longer hospitalization, extra studies, etc.) indicate in detail how this will be handled. In cases where the FDA has authorized the drug or device company to charge the patient for the experimental drug or device,* ***a copy of the authorization letter from the FDA or sponsor must accompany the application. Final approval will not be granted until the IRB receives this documentation.***
There are very limited circumstances under which study participants may be responsible (either directly or via their insurance) for covering some study-related expenses. If the study participant or their insurer(s) will be billed for any portion of the research study, provide a justification as to why this is appropriate and acceptable. For example, if the study involves treatment that is documented standard of care and not investigational, state so. In these cases, the protocol and the consent should clearly define what is standard of care and what is research.

No expenses are anticipated for participants.

Payment for participation: *Describe all plans to pay subjects, either in cash, a gift or gift certificate. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive. The amount of payment must be justified. Clarify if subjects will be reimbursed for travel or other expenses.*

☐ ***Not applicable***

Participants will be offered small tokens for completing data collection. Items such as small kitchen equipment, cookbooks, gift cards, etc. (value of $ 5-25) will be provided to those who provide follow-up data.

Collaborating Sites*. When research involving human subjects will take place at collaborating sites or other performance sites when UVM/UVM Medical Center is the lead site, the principal investigator must provide in this section a list of the collaborating sites and their Federalwide Assurance numbers when applicable. (agreements may be necessary)*

X ***Not applicable***

INFORMED CONSENT

Consent Procedures*: Describe the consent procedures to be followed, including the circumstances under which consent will be obtained, who will seek it, and the methods of documenting consent. Specify the form(s) that will be used e.g. consent (if multiple forms explain and place identifier on each form), assent form and/or HIPAA authorization (if PHI is included). These form(s) must accompany the protocol as an appendix or attachment.*

Note: Only those individuals authorized to solicit consent may sign the consent form confirming that the prospective subject was provided the necessary information and that any questions asked were answered.

Cooking Class Condition

Interested persons will be directed to a secure online recruitment survey which queries for basic contact information, demographic information, and eligibly criteria. Individuals who appear likely to be eligible based on this online application will be asked to sign up for an in-person information session. This online application will collect information from applicants prior to informed consent, thus a waiver of consent form has been included.

At the information session applicants will receive detailed information regarding the study interventions, the randomization process, and data collection procedures. During the information session designated staff who have been certified to obtain consent will discuss the informed consent form with the subject volunteer, reviewing each aspect of the consent form and allowing individuals to ask questions. This information session may be delivered in a group setting, although if scheduling does not permit engaging in the group session, the subject volunteer may be orientated individually. Potential participants often benefit from the group process in that they hear questions that others ask which may not have occurred to them but are of interest to them in their decision making about participation. Participants will be provided with a copy of the consent form at the group session but will not be asked to sign the form until they have had a chance to review the consent form fully. The person obtaining consent will be an individual who has been certified to obtain consent for the study and this person will thoroughly explain each element of the document and outline the risks and benefits, and follow-up requirements of the study. Participant privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. All signatures and dates will be obtained. A copy of the signed consent will be given to the participant. The informed consent process will be documented in each subject's research record.

Following informed consent, the remainder of screening will be conducted (e.g., self monitoring diary completed, discussion of randomization acceptance) and baseline data will be collected. Individuals who remain interested in the study after the session and have reviewed the consent form will be invited to complete baseline data collection online and then return for an individual screening session at which the remainder of the screening process will occur.

Control Condition

At the conclusion of recruitment for the Cooking Class Condition, those who completed the initial application, but did not go farther in the recruitment process will be asked if they would like to participate in the control arm of the study. To participate, they will be asked to attend an Office Hours appt. with the PI or Study Coordinator to fill out informed consent and then will be given access to the baseline data collection online. Those in the Control Condition will also then be randomized to either receive meal kits and recipes in Phases 2 and 3 of the study, or to receive no further support. The contact information and screening information of participants who decline consent will be destroyed.

Information Withheld From Subjects: *Will any information about the research purpose and design be withheld from potential or participating subjects? If so, explain and justify the non-disclosure and describe plans for post-study debriefing.*

X ***Not applicable***

Attach full grant application, including budget information and/or any contract or draft

contract associated with this application.

All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the InfoEd Resource Materials page for more information.